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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,773	11/04/2003	Hongming Chen	TPIP020	5482
27777	7590	01/22/2008	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			HYUN, PAUL SANG HWA	
			ART UNIT	PAPER NUMBER
			1797	
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			01/22/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/700,773

Applicant(s)

CHEN ET AL.

Examiner

Paul S. Hyun

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-22 is/are pending in the application.
- 4a) Of the above claim(s) 1-5 and 7-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/ are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### REMARKS

Claims 1-5 and 7-22 are currently pending, with claims 1-5 and 7-18 being withdrawn pursuant to the restriction requirement dated 12/29/06. In summary claims 19-22 are currently pending for examination on the merits.

The claim rejection under 35 U.S.C. section 112 cited in the previous Office action has been withdrawn in light of the amendments.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims **19-22** are rejected under 35 U.S.C. 103(a) as being unpatentable over McMahon et al. (US 6,004,967) in view of Lee et al. (US 2003/0230488 A1) as evidenced by [www.wikipedia.com](http://www.wikipedia.com).

McMahon et al. disclose a method for determining the solubility of pharmaceutical compound A1 (see Table 1 in col. 19 for identity of A1) in various excipients wherein the pharmaceutical preparation can comprise solids or non-aqueous liquid (see lines 6-48, col. 17 and Table 4 in col. 20). Specifically, Table 4 shows the

solubility of compound A1 having concentration of 10 mg/mL in two different concentrations of polysorbate-80 excipient. Polysorbate-80 has viscosity ~300-500 cP (see wikipedia.com wherein unit conversion for viscosity from cSt to cP is accomplished by multiplying viscosity of polysorbate-80 in cSt by its density in g/mL). The method disclosed by McMahon et al. differs from the claimed invention in that McMahon et al. do not disclose the steps of conducting the experiment in an array format. McMahon et al. also do not disclose the step of dispensing less than 250 microliters of the excipient using a positive displacement pump.

Lee et al. disclose an apparatus for conducting solubility tests (see [0005]). The apparatus comprises a microplate 12 (see [0047]), and a positive displacement pump (see [0039]) capable of dispensing 2-10 microliters of highly viscous liquid into the wells of the microplate (see [0067]-[0068]). In light of the disclosure of Lee et al., it would have been obvious to one of ordinary skill in the art to conduct the solubility test disclosed by McMahon et al. using the apparatus disclosed by Lee et al. The apparatus disclosed by Lee et al. would optimize the organization as well as the efficiency of the solubility test.

Although neither McMahon et al. nor Lee et al. explicitly disclose the step of ranking the compounds based on solubility, it would have been obvious to one of ordinary skill in the art to do so once all the samples have been tested. Organizing data according to increasing or decreasing value is within the skill of one of ordinary skill in the art.

With regards to claim 20, neither McMahon et al. nor Lee et al. explicitly disclose that degraded or decomposed samples are thrown out from the experiment.

Nonetheless, it would have been obvious to one of ordinary skill in the art to selectively exclude decomposed or degraded samples to prevent skewed data caused by defective samples.

With respect to claim 21, it would have been obvious to one of ordinary skill in the art to expand the range of parameters (e.g. concentration of excipient, type of excipient) in the method disclosed by McMahon et al. such that more than 94 samples are prepared so that a more thorough data can be obtained.

#### ***Response to Arguments***

Applicant's arguments with respect to the art rejection have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground of rejection has been made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul S. Hyun whose telephone number is (571)-272-8559. The examiner can normally be reached on Monday-Friday 8AM-4:30PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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PSH  
1/15/08

  
Jill Varden  
Supervisory Patent Examiner  
Technology Center 1700